K021084
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EXHIBIT A – 510(k) SUMMARY
MINRAD, Inc. LIGHT SABER™ SPINAL NEEDLE

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

JUL 3 2002

MINRAD, INC.
847 Main Street
Buffalo, NY 14203

Phone: (716)-855-1068
Facsimile: (716)-855-1071

Contact Person: Kim S. DeVitto
Registration Manager

Date Prepared: March 28, 2002

Name of Device and Name/Address of Sponsor

Light Saber™ Spinal Needle

MINRAD, INC.
847 Main Street
Buffalo, NY 14203

Common or Usual Name

Spinal Needle

Classification Name

General and Plastic Surgery Devices

Predicate Devices

1. Spinal Needle, Ballard Medical Products
2. Light Saber™ Aspiration Needle, MINRAD, Inc.

Intended Use

The Light Saber™ Spinal Needle is a single use disposable spinal needle/cannula intended for the injection of fluid into or aspiration of fluid from the body. This device is indicated for use with MINRAD Inc.'s Dual Radiation Targeting System™ (DRTS) to improve the accuracy of needle placement.

EXHIBIT A – 510(k) SUMMARY
MINRAD, Inc. LIGHT SABER™ SPINAL NEEDLE

Technological Characteristics

The Light Saber™ Spinal Needle consists of a needle and a collimator to which a stylet is attached. The stylet is enclosed in a cannula/hub assembly with a matching tip. The female Luer of the cannula hub, for the attachment to the syringe, is designed to comply with ISO-594 for *"Conical Fittings with a 6% (Luer)Taper for Syringes, Needles and Other Medical Equipment."* The Light Saber™ Spinal Needles are provided in gauges of 18, 20, 22, 23, and 25. The Light Saber™ Spinal Needle will be provided in lengths of 3.75, 6.25, 8.75, 15 and 20 cm. The tip design for these needles will provide either a Quincke, Short Bevel or Chiba point. Depth markings are standard on the cannula.

Substantial Equivalence

The MINRAD, Inc. Light Saber™ Spinal Needle is substantially equivalent to the predicate devices referenced above. Except for minor differences in general indications for use, size of the needle and needle tip configurations, the MINRAD, Inc. Light Saber™ Spinal Needle is identical to its predicate devices. These minor differences raise no new issues of safety or effectiveness. Thus, the MINRAD, Inc. Light Saber™ Spinal Needle is substantially equivalent to its predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 3 2002

Ms. Kim S. DeVitto
Registration Manager
Minrad, Inc.
847 Main Street
BUFFALO NY 14203

Re: K021084
Trade/Device Name: Light Saber™ Spinal Needle
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston syringe
Regulatory Class: II
Product Code: 80 FMF
Regulation Number: 21 CFR 892.5780
Regulation Name: Light beam patient position indicator
Regulatory Class: I
Product Code: 90 IWE
Dated: April 2, 2002
Received: April 4, 2002

Dear Ms. DeVitto:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

EXHIBIT H

INDICATIONS FOR USE

Indications for Use Form

510(k) Number (if known): K021084

Device Name: Light Saber™ Spinal Needle

Intended Use: A single use disposable spinal needle/cannula intended for the injection of fluids into or retraction of fluids from the body.

Indications for Use: A single use disposable spinal needle/cannula indicated for the injection or retraction of fluids from the body during surgical procedures. This device is indicated for use with MINRAD INC.'s Dual Radiation Targeting System™ (DRTS) to improve the accuracy of needle placement.

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use____
(Per 21 C.F.R. 801.109)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K021084